DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 7,2014

Eco Medi Glove SDN BHD
Mr. Suresh Kumar
Quality Assurance Manager
Lot 23836, Jalan Tembaga Kuning
Kamunting Raya Industrial Estate
Kamunting Perak, Malaysia 34600

Re: K141623
Trade/Device Name: EMG Blue Nitrile Examination Gloves Powder Free with Tested for Use with Chemotherapy Drugs Labeling Claim
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Glove
Regulatory Class: I
Product Code: LZA, LZC
Dated: September 5, 2014
Received: September 5, 2014

Dear Mr. Suresh Kumar:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K141623

Device Name
EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy Drugs

Indications for Use *(Describe)*
A Powder Free Examination Glove is a disposable device intended for Medical Purpose that is worn on the examiner's hand of fingers to prevent contamination between patient and examiner and for use with Chemotherapy Drugs
In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by Chemotherapy drugs

Chemotherapy Drug and concentration	Minimum Breakthrough detection time in Minutes,0.01μg/cm²/minute
1)Carmustine (BCNU) (3.3mg/ml)	1.3 minutes
2)Cyclophosphamide (20mg/ml)	> 240 minutes
3)Cytarabine (100mg/ml)	> 240 minutes
4)Doxorubicin Hydrochloride (2 mg/ml)	> 240 minutes
5)Etoposide (20mg/ml)	> 240 minutes
6)Fluorouracil (50mg/ml)	> 240 minutes
7)Methorexate (25mg/ml)	> 240 minutes
8) Paclitaxel (6mg/ml)	> 240 minutes
9) Thiotepa (10mg/ml)	67.8 minutes

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time :
Carmustine (BCNU) (3.3mg/ml)
Thiotepa (10mg/ml)

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

510(K) Summary
EMG Blue Nitrile Examination Gloves Powder Free with Tested for use with Chemotherapy Drugs

1.0 Submitter :

Company Name : ECO MEDI GLOVE SDN. BHD.

Company Address : Lot 23826,Jalan Tembaga Kuning
Kamunting Raya Industrial Estate,
34600,Kamunting Perak
Malaysia.

Contact Person : Mr Suresh Kumar

Telephone No : 603-60283033

Email : suresh@ecomediglove.com.my

2.0 Preparation Date : 23rd September 2014

3.0 Name of the Device

Trade Name / Proprietary Name : EMG Blue Nitrile Examination Gloves
Powder Free with tested for use with
Chemotherapy drugs.

Device Name : Nitrile Patient Examination gloves.

Device Classification Name : Patient Examination gloves (21 CFR 880.6250).

Device Class : Class I.

Product Code : Nitrile-LZA and LZC.

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

4.0) Identification of The Legally Marketed Device :

Class I patient Examination glove with tested for use with Chemotherapy Drugs, Powder Free,LZC, which meets all the requirement of ASTM D 6319-10 and FDA 21 CFR 880.6250.It is equivalent to K110921, Cornflower Powder Free Exam glove tested for use with Chemotherapy Drugs (Non sterile) .

5.0 Device Description

The subject device in this 510(k) Notification is Blue Nitrile Examination gloves, powder free, with tested for use with Chemotherapy drugs. The subject device is a patient examination glove made from nitrile latex compound, Blue colour, powder free and non sterile (Per 21 CFR 880.6250, class I). The device meets all the specifications in ASTM D6319-10, Standard specification for Nitrile Examination Gloves. Additionally, the gloves have been tested for biocompatibility and permeability to chemotherapy drugs.

The Blue Nitrile Medical Examination Gloves, Powder Free, is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner (product Code LZA) and is used with chemotherapy drugs (Product code LZC). The subject device is substantially equivalent to the legally marketed Nitrile Medical Examination Gloves (product Code LZA and LZC).

6.0 Specification for Nitrile gloves:
6.1 Dimension and Thickness of Gloves

Dimension	Size S	Size M	Size L	Size XL
Overall Length (mm)	270min	270min	270min	270min
Width (± 5mm)	85	95	105	115
Thickness at Palm (mm)	0.10min	0.10min	0.10min	0.10min
Thickness at Finger Tip (mm)	0.10min	0.10min	0.10min	0.10min

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

6.1.2 Gloves Physical Properties and Holes

Measurement	Before Ageing	After Aging at 70°C for 168 hrs @ 100°C for 22 hrs
Tensile Strength (MPa)	14min	14 Min
Ultimate Elongation (%)	500min	400min
Pin-hole Level	AQL 2.5 Inspection Level G-1	AQL 2.5 Inspection Level G-1

Gloves meet all the specification listed in ASTM D 6319-10

Characteristics	**Acceptance Criteria**	**EMG Blue Nitrile Medical Examination Gloves Powder Free with tested for use with chemotherapy drugs (K141623)**	**Nitrile Cornflower Blue Powder Free gloves tested for use with Chemotherapy drugs (Non-Sterile), K110921**
Product Code	LZC	LZC	LZC
Intended use	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.	A powder free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner. The device is for over-the-counter use.
Material use	Nitrile latex compound	Nitrile latex compound	Nitrile latex compound
Colour	Blue	Blue	Blue
Sterility	Non sterile	Non sterile	Non sterile
Single used	Single used	Single used	Single used
Non Sterile	Non Sterile	Non Sterile	Non Sterile Section 2A-3

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

Dimensions	Overall Length (mm) Min 270mm Width (± 5mm) **Size S = 85mm** **Size M = 95mm** **Size L = 105mm** **Size XL = 115mm** Thickness at Palm (mm) Min; 0.10mm Thickness at Finger Tip (mm) Min 0.10 mm	Meets ASTM D6319-10	Meets ASTM D6319-10
Physical properties	**Before Ageing** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 500min **After Aging at 70°C for 168 hrs @ 100°C for 22 hrs** Tensile Strength (MPa) = 14min Ultimate Elongation (%) = 400min	Meets ASTM D6319-10	Meets ASTM D6319-10
Freedom from pinholes	AQL 2.5 Inspection Level G-1	Meets ASTM D5151-06	Meets ASTM D5151-06
Residual Powder	≤ 2.0 mg/pc	Meets ASTM D6124-06	Meets ASTM D6124-06
Biological Evaluation on Medical Device - -Primary Skin Irritation Test		Under the conditions of this study, the test article was a non-irritant.	Under the conditions of this study, the test article was a non-irritant.
Biological Evaluation on Medical Device - Dermal Sensitization Assay		Under the conditions of this study, the test article was a non-sensitizer.	Under the conditions of this study, the test article was a non-sensitizer.
Resistance against Chemotherapy Drugs		1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 1.3 min.	1) Carmustine (3.3mg/ml or 3000ppm), Breakthrough : 4.5min.

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

	Standards Practice for Assessment of resistance of Medical Glove to Permeation by Chemotherapy drugs ASTM D6978-05(2013)	2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 3) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : >240 min. 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 min. 7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min. 8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min. 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 67.8 min.	2) Cyclophosphamide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 3) Cytarabine (100mg/ml or 100,000ppm), Breakthrough time : >240 min. 4)Doxorubicin Hydrochloride (2.0mg/ml or 2000ppm), Breakthrough time : >240 min. 5) Etoposide (20mg/ml or 20,000ppm), Breakthrough time : >240 min. 6) Flourouracil (50mg/ml or 50,000), Breakthrough time : >240 min. 7) Methorexate (25mg/ml or 25,000ppm), Breakthrough time : > 240 min. 8) Paclitaxel (6mg/ml or 6,000ppm), Breakthrough time : >240 min. 9) Thiotepa (10mg/ml or 10,000ppm), Breakthrough time : 6.88 min.

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

7.0 Intended use of the Device

A powder-free patient examination glove is a disposable device intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner and for use with chemotherapy drugs . It is for over-the-counter use.

In addition these gloves were tested for use with Chemotherapy drugs in accordance with ASTM D6978-05 standards Practice for assessment of Medical Glove to Permeation by chemotherapy drugs.

Chemotherapy Drug and concentration	**Minimum Breakthrough detection time in Minutes,0.01µg/cm²/minute**
1)Carmustine (BCNU) (3.3mg/ml)	**1.3 minutes**
2)Cyclophosphamide (20mg/ml)	**> 240 minutes**
3)Cytarabine (100mg/ml)	**> 240 minutes**
4)Doxorubicin Hydrochloride (2 mg/ml)	**> 240 minutes**
5)Etoposide (20mg/ml)	**> 240 minutes**
6)Fluorouracil (50mg/ml)	**> 240 minutes**
7)Methorexate (25mg/ml)	**> 240 minutes**
8) Paclitaxel (6mg/ml)	**> 240 minutes**
9) Thiotepa (10mg/ml)	**67.8 minutes**

The maximum testing time is 240 minutes. Please note that the following drugs have extremely low permeation time.

Carmustine (BCNU) (3.3mg/ml)
Thiotepa (10mg/ml)

ECO Medi Glove Sdn. Bhd. (815262-D)
(formerly known as Sinetimed Consumables Sdn. Bhd.)
Lot 23826, Jalan Tembaga Kuning, Kamunting Raya Industrial Estate, 34600 Taiping. Perak Darul Ridzuan. **MALAYSIA.**
TEL +60-5-891 2777 FAX +60-5-891 2999

Appendix 2
(510k#: K141623)

8.0 Summary of the Technological Characteristics of the Device compared to the Predicate Device for substantial equivalent discussion

There are no differences in technological characteristics of the subject device compare with the predicate device.

The gloves are made from nitrile latex compound, Blue colour, Powder free and non-sterile. The gloves met all the specifications in ASTM D6319-10 Standard specification for Nitrile Examination Gloves as well Biological Evaluation on medical device. Additionally, the gloves have been tested for permeability to chemotherapy drugs.

Based on the intended uses, physical properties and technological characteristics, the subject device is as safe and effective as a legally marketed device- K110921, Nitrile Cornflower Blue Powder Free Exam Gloves Medical Exam tested for use with Chemotherapy Drugs test, and its does not raise different questions of safety and effectiveness.

9.0 Conclusion

Based on intended uses, technological characteristics and non – clinical performance data, the EMG Blue Nitrile Examination Gloves Powder Free with tested for use with Chemotherapy Drugs (K141623) is substantially equivalent to the predicate device (K110921).